

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact: PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121
Tel: 858-550-3800 x 2506 – Fax: 858-550-3813
Attn: Mr. Hartmut Loch, RAC
Director, Regulatory Affairs

Trade name: GALILEO CAS/NAV TKR System

Common name: Navigation System

Classification name: Instrument, Stereotaxic
§ 882.4560, Class II, Neurologic Device Panel 82

Product Code: HAW

Device Description and Characteristics: The GALILEO CAS/NAV TKR System is a system for computer-assisted navigation of the GALILEO-CAS instruments with the aim to position TC-PLUS™ Solution Knee prostheses optimally for the patient. The collection of patient data required for this occurs exclusively operatively. A preoperative CT scan is not necessary. The connection between patient and computer is made via two infrared transmitters (active locators), which are attached to the distal femur and to the proximal tibia. Two passive locators are used for the spatial arrangement of the instruments. A manual navigation key button is used for scanning the anatomical bone features (landmarks). An infrared camera locates the locators as well as the manual key button and is connected to the computer. The computer-assisted Galileo CAS Total Knee Replacement System supports the operating surgeon performing the total knee replacement procedure. The system takes the femur-cutting device to the required position and enables resections with high accuracy and flexibility.

Due to the precise computer-assisted references and the correct positioning of the cutting device the bone resections can be performed with the utmost accuracy.

The Galileo CAS system essentially consists of two components, the electronic components and the instruments, which are attached to the distal femur. The instruments, which are driven by small electric (low-voltage) motors, are controlled by the computer, to ensure correct positioning of the femur-cutting device.

Equivalence: The GALILEO CAS/NAV TKR System is substantially equivalent to the OrthoPilot® (Aesculap, Inc. – K003347 – S/E 2/23/2001). Both systems are intended for the same medical indications and are technically similar.

Indications: The GALILEO CAS/NAV TKR System is intended for computer-assisted navigation of the GALILEO-CAS instruments with the aim to position the implants of the TC-PLUS™ Solution Knee (K000666 – S/E 10/13/00) optimally for the patient.

Performance data: Biomechanical tests have been performed. The test results were equivalent to other similar implants and are sufficient for in vivo loading.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2002

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
Plus Orthopedics
6055 Lusk Boulevard
San Diego, CA 92121-2700

Re: K020298
Trade/Device Name: GALILEO CAS/NAV TKR System
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: April 12, 2002
Received: April 15, 2002

Dear Mr. Loch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

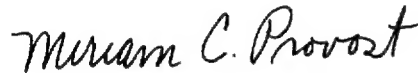
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



for Celia Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number: K020298

Device Name(s):

GALILEO CAS/NAV TKR SYSTEM

Indications for Use:

The GALILEO CAS/NAV TKR System is intended for computer-assisted navigation of the GALILEO-CAS instruments with the aim to position the implants of the TC-PLUS™ Solution Knee (K000666 – S/E 10/13/00) optimally for the patient.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020298Prescription Use X OR Over-The-Counter-Use _____

(Per 21 CFR 801.109)

(Optional format 1-2-96)